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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/052,855	03/31/1998	PATRICIA A. BILLING-MEDEL	6064.US.P1	9597

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STEVEN F. WEINSTOCK
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/052,855	BILLING-MEDEL ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *44-48 and 50-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *44-48, 50-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 1-9, 17-24, 26-29, 31-34, 36, 37 and 49. Claims 44-48 and 50-58 are under consideration.

2. The text of Title 35 US Code not recited in this action can be found in a previous action.

3. Claims 54, 55 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 54, 55, and 58 appear to encompass polynucleotides encoding "the complete complements" of amino acid sequences. It is unclear what amino acid sequence this encompasses, as a given amino acid residue does not have a complementary amino acid residue analogous to the purines and pyrimidines of nucleic acids.

Claim 58 is drawn in part to a polynucleotide consisting of a sequence selected from the group consisting of SEQ ID NO:24-28. The metes and bounds of the claim is unclear as SEQ ID NO:24-28 are amino acid sequences, not polynucleotide sequences.

4. The objection to claim 53 under 37 CFR 1.75 as being a substantial duplicate of claim 51 is maintained for reasons of record. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, the limitation "comprising a polynucleotide encoding at least one epitope" is inherent in the polynucleotides of claim 50, and is therefore inherent within the cell of claim 51. applicant argues that due to the dependency of claim 51 on claim 50, which is drawn to a recombinant expression system, rather than a cell, claim 51 differs from claim 53. This has been considered but not found persuasive. Claim 51 is drawn to an isolated cell transfected with the recombinant expression system of claim 50. As such, claim 51 is not dependent on claim 50, because an isolated cell cannot further limit the scope of claim 50, Claim 51 is using the reference to claim 50 as a "shorthand" for

characterizing the expression system with which the cell is transfected. Thus, claims 51 and claim 53, both drawn to cells, have the same scope.

5. The rejection of claims 44-48, 50, 53, 56, 57 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons of record.

The instant claims recite "degenerate coding sequences thereof" without reference to a protein sequence which is being encoded, as SEQ ID NO:1-9, 12 and 13 are all polynucleotide sequences.

Applicants amendments which restate that the degenerate coding sequences are from SEQ ID NO:1-9, 12 and 13 do not overcome this rejection.

6. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 52 recites "expression vector containing a polynucleotide sequence encoding a polypeptide consisting of an amino acid sequence selected fro the group consisting of SEQ ID NO:24-28 and the complete complements and degenerate coding sequences of SEQ ID NO:1-9, SEQ ID NO:12 and SEQ ID NO:13. It is unclear how the complete complements and degenerate coding sequences can belong to a Markush group describing an amino acid sequence.

7. The rejection of claim 52 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a polypeptide comprising expressing the polynucleotides encoding SEQ ID NO:24-28, does not reasonably provide enablement for a method of producing a polypeptide comprising expressing the complete complement of the polynucleotides encoding SEQ ID NO:24-28 is maintained for reasons of record. Amended claims 54, 55 and 58 are also included with this rejection because it is not clear what a complementary sequence to an amino acid encompasses.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. .

Claim 52 is drawn in part to a method for producing a polypeptide comprising incubating host cells that have been transfected with a polynucleotide sequence encoding an amino acid sequence selected from the group consisting of the complete complements of SEQ ID NO:24-28.

Claim 54 is drawn in part to a purified polynucleotide which encodes the complete complement of the sequences SEQ ID NO:24-28. Claim 55 is drawn in part to a purified polynucleotide which encodes the complete complement of the sequences SEQ ID NO:24 and 25. The metes and bounds of claim 58 are unclear for the reason set forth in the rejection under 112, second paragraph above. However, claim 58 might be drawn to a purified polynucleotide encoding the complete complement of SEQ ID NO:24-28.

The specification teaches that the polypeptide of SEQ ID NO:24 is expressed from SEQ ID NO:13. If the complete complement of SEQ ID NO:13 were substituted for SEQ ID NO:13, the resulting transcribed protein would not be structurally or functionally related to SEQ ID NO:24. The specification teaches that SEQ ID NO:25-28 are fragment of SEQ ID NO:24 that were used to raise antibodies, if the complete complements of the polynucleotides encoding SEQ ID NO:25-28 were substituted in an expression vector, the amino acid sequence produced would not generate antibodies which bound to the same sequences as the antibodies which bound to SEQ ID NO:25-28. It is reasonable to assume that these polypeptides would not be representative of the polypeptides associated with colon cancer as taught in the instant specification. Accordingly, the specification is not enabling for how to use the proteins produced by a method which comprises the recombinant expression of the complements of the polynucleotides encoding SEQ ID NO:24-28. One of skill in the art would be subject to undue experimentation in order to use all the proteins of the broadly claimed method.

Applicant argues "The specification at lines 20-25 of page 47, states that antibodies generated against a polypeptide comprising a sequence of the present invention can be obtained by direct injection of the polypeptide into an animal or by administering the polypeptide to an animal such as a mouse, rabbit, goat or human. The polypeptide is selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof.". This has been considered but not found persuasive. The claim is rejected under 112, first paragraph based on lack of enablement for how to use a polypeptide produced by the expression of the complete

complement of the polynucleotides encoding SEQ ID NO:24-28. As stated above, If the complete complements of the polynucleotides encoding SEQ ID NO:25-28 were substituted in an expression vector, the amino acid sequence produced would not generate antibodies which bound to the same sequences as the antibodies which bound to SEQ ID NO:25-28. It is reasonable to assume that these polypeptides would not be representative of the polypeptides associated with colon cancer as taught in the instant specification. Accordingly, the specification is not enabling for how to use the proteins produced by a method which comprises the recombinant.

8. Claims 50, 51, 53 and 57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotide sequences comprising the sequence of SEQ ID NO:1-9. The specification identifies said sequences as partial EST sequences (page 56, lines 1-10). The specification does not address whether the partial sequences comprise intron/exon splice junctions. When given the broadest reasonable interpretation, the claims can be interpreted as reading on genomic sequences, including any full length gene which comprises each of the sequence. Thus, each EST sequence represents a genus of polynucleotides.

The disclosure of a single species of a genus may provide adequate written description of the genus which the species disclosed is representative of the genus. The present claims encompass full length genes, cosmids and chromosomes comprising said genes. Eukaryotic chromosomes and genes are expected to comprise regulatory regions and untranslated intron regions. These regions are not disclosed by the specification. There is substantial variability among the species of polynucleotides encompassed by the genuses because SEQ ID NO:1-9 represent only a fragment of any full length gene or chromosome. Functional attributes such as coding capacity cannot be relied upon to distinguish partial sequence from complete genes and chromosomes because complete genes and chromosomes also would encode the sequence which was deduced from the analysis of the combined partial sequences (SEQ ID NO:24). Amendment of the claims to polynucleotide consisting of SEQ ID NO:1-9 would overcome this rejection.

Applicant has amended claim 50 to recite "expression system comprising a nucleic acid sequence... wherein said nucleic acid sequence consists of a polynucleotide having a sequence selected from the group consisting of SEQ ID NO:1-9, 12 and 13". This has been considered but not found persuasive. The terms "comprising" and "having" are open terms, both of which negate the single limitation of "consists of". Claim 52 has been amended to include the partial nucleic acid sequences of SEQ ID NO:1-9, 12 and 13. A vector "containing" a polynucleotide sequence which consist of said partial sequence reads on a vector which comprises said sequence, and thus the limitation of "consisting of" fails to limit the claim scope. . It is noted that claim 52 is rejected under 112, second paragraph as being vague and indefinite in scope. Claim 53 is drawn to a n isolated cell transfected with a nucleic acid sequence which comprises a polynucleotide consisting of SEQ ID NO:1-9, 12 or 13. Again, the limitation of a "comprising a polynucleotide" negates the limitation of "consisting of".

9. The rejection of claims 50-53 under 35 U.S.C. 102(e) as being anticipated by Yu et al (U.S. 5,733,748) is maintained for reasons of record.

Yu et al disclose Sequence 6 which comprises the instant SE ID NO:7 at nucleotides 10-237 and the instant SEQ ID NO:8 at nucleotides 144-394. Yu et al disclose expression vectors comprising Sequence 6 which operable link the disclosed sequence to a operable promoter, host cells comprising said expression vectors and method of producing recombinant proteins (column 12, line 16 to column 15, line 7). Yu et al disclose that said polynucleotides may be synthetic or recombinant and include both the coding and the anti-sense strand (column 4, lines 62-67), thus fulfilling the specific embodiments of a sequence "having" SEQ ID NO:7 or SEQ ID NO:8 and the complete complements thereof.. Yu et al disclose a kit comprising a container filled with one or more ingredients of the invention for human administration (column 16, lines 60-63). Yu et al disclose the antisense constructs of Sequence 6 as a pharmaceutical composition. Therefore, Yu et al disclose a kit comprising the complete complement of Sequence 6, which would anticipate a kit comprising a polynucleotide having a sequence selected from the group consisting of the complete complement of SEQ ID NO:7 and SEQ ID NO:8. Yu et al also disclose Sequence 7 which comprises the sequence of SEQ ID NO:27 at residues 45-81 and SEQ ID NO:28 at residues 90-129. Yu et al disclose a process of producing Sequence 7 comprising culturing

recombinant prokaryotic or eukaryotic host cells in culture under conditions promoting expression of said protein and subsequently recovering said protein (column 2, lines 58-64).

Applicants amendments to claims 50-53 did not suffice to produce a claim which was limited in scope to the disclosed fragment rather than nucleotides comprising said fragments for the reasons set forth in the above paragraph. Accordingly the art rejections are maintained.

10. All other rejections and objections as set forth in the previous office action are withdrawn in light of applicants amendments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (571) 272-0828. The examiner can normally be reached on Monday through Friday from 9 am to 6:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 272-0871. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Primary Examiner, Group 1642

January 23, 2004

Karen A. Canella